

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: Application of Michael John MONTEITH et al.

International Application No.: PCT/EPEP2004/007666

International Filing Date: July 8, 2004

For: Pharmaceutical Formulations Comprising Magnesium Stearate

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

☒ Copies of the references are enclosed

☐ Copies of the references were submitted in parent application Serial No. \_\_\_\_\_.  
(37 CFR 1.98(d))

☒ A copy of the International Search Report which issued on International Application No. \_\_\_\_\_ PCT/EP2004/007669 is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

A. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

OR

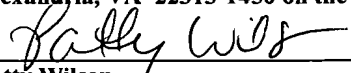
☐ The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).

B. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but **before** the mailing date of either:  
(1) a final action under § 1.113 or  
(2) a notice of allowance under § 1.311,  
whichever occurs first.

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Patty Wilson

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$180.00).
- C. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. **[or]**
- ☐ Applicant hereby certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this statement; and
- ☐ The petition fee set forth in § 1.17(i)(1) (\$180.00) is submitted herewith.
- ☒ Please charge any required fees to Deposit Account No.07-1392.
- ☐ A duplicate copy of this paper is attached.

Respectfully Submitted,

  
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**FORM PTO-1449**  
**INFORMATION DISCLOSURE STATEMENT**

INT'L FILING NO.	PCT/EP2004/007666
INT'L FILING DATE	7/8/2004
APPLICANT	Michael Monteith et al.
GROUP	
EXAMINER	
ATTORNEY DOCKET NO.	PB60385USw

**U.S. PATENT DOCUMENTS**

Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	1.	5,202,309	4/13/1003	Schwartz et al.			
	2.	6,576,793	6/10/2003	Moran et al.			
	3.	6,747,043	6/8/2004	Moran et al.			

**FOREIGN PATENT DOCUMENTS**

		Document Number	Publication Date	Country	Class	Subclass	Translation Yes   No
	4.	0069715	1/12/1983	EP			
	5.	0237507	9/16/1987	EP			
	6.	2064336	6/17/1981	GB			
	7.	2129691	5/23/1984	GB			
	8.	2169265	7/9/1986	GB			
	9.	2178965	2/25/1987	GB			
	10.	2242134	9/25/1991	GB			
	11.	WO96/23485	8/8/1996	PCT			
	12.	WO00/28979	5/25/2000	PCT			yes-abstract
	13.	WO00/53158	9/14/2000	PCT			
	14.	WO01/42193	6/14/2001	PCT			
	15.	WO01/78694	10/25/2001	PCT			
	16.	WO01/78695	10/25/2001	PCT			
	17.	WO02/070490	9/12/2002	PCT			
	18.	WO02/076933	10/3/2002	PCT			
	19.	WO02/078671	10/10/2002	PCT			yes-abstract
	20.	WO03/024439	3/27/2003	PCT			
	21.	WO03/057194	7/17/2003	PCT			
	22.	WO03/091204	11/6/2003	PCT			
	23.	WO03/072539	9/4/2003	PCT			
	24.	WO03/088943	10/30/2003	PCT			
	25.	WO03/088944	10/30/2003	PCT			
	26.	WO04/022547	3/18/2004	PCT			
	27.	WO04/037768	5/6/2004	PCT			
	28.	WO04/037773	5/6/2004	PCT			
	29.	WO04/016578	2/25/2004	PCT			
	30.	WO04/037807	5/6/2004	PCT			
	31.	WO04/039762	5/13/2004	PCT			
	32.	WO04/039766	5/13/2004	PCT			
	33.	WO05/004845	1/20/2005	PCT			
	34.	WO05/004852	1/20/2005	PCT			

**OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)**

35.	WIRTH et al., Maillard Reaction of Lactose and Fluoxetine Hydrochloride, a Secondary Amine, J. of Pharm. Sciences <b>87(1)</b> :31-39 (1998).
36.	HAMMOUDA et al., Lactose-induced Discoloration of Amino Drugs in Solid Dosage Form, Kurze Originalmitteilungen <b>25</b> :181 (1970).
37.	KUMAR et al., Maillard Reaction and Drug Stability, Royal Soc. of Chemistry <b>151</b> :20-27 (1999).
38.	ZENG et al., The role of fine particle lactose on the dispersion and deaggregation of salbutamol sulphate in an air stream in vitro, Int'l J. of Pharmaceutics <b>176</b> :99-110 (1998).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.